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July 27, 2004

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Docket Number: 2002N-0085 (Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food

Via E-Mail: fdadockets@oc.fda.gov

Docket Officer:

The American Industrial Hygiene Association (AIHA) appreciates the opportunity to provide input and offer comments and recommendations to the Food and Drug Administration on a proposed rule regarding requirements pertaining to sampling services and private laboratories used in connection with imported food. The proposed rule was announced in the *Federal Register* on April 29, 2004, page 23460. The Docket Number is 2002N-0085.

Founded in 1939, AIHA is a nonprofit association comprised of 12,000 members and more than 75 local sections. AIHA members serve on the front line of health and safety every day to protect workers, their families and the community.

AIHA wishes to provide specific comments on the proposed rule adding in 21 CFR a new part 59 entitled "Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food". AIHA supports efforts by the FDA to assure the important role that private laboratories play in demonstrating that imported food products comply with laws and regulations administered by FDA. Because of the increased concern by the United States to protect our food supply and the potential for bioterroism attacks, it is imperative that laboratories use validated or recognized analytical methods. The integrity and scientific validity of data and results is required.

In the "supplementary information" portion of the proposed rule, the FDA highlighted its discussion about whether or not the private laboratories used in evaluating imported foods should be required to be accredited. Again in Subpart D (page 23463) the Agency described its careful

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consideration whether to require the accreditation of private laboratories subject to proposed part 59. Given all considerations, the FDA decided to omit a laboratory accreditation requirement from the proposed rule. The Agency went on to say that "while the agency strongly encourages laboratories to become accredited, questions about the accreditation standard to be used, how the FDA would ensure that the accrediting body is a recognized or competent accrediting body, and other issues suggest that it would be premature for the FDA to propose requiring private laboratories to be accredited."

AIHA strongly disagrees with this view and recommends amending the proposed rule to require that these private laboratories meet accreditation standards.

AIHA believes there are several accrediting bodies within the U.S. that can reliably validate the data generated by private laboratories through the laboratory's demonstrated compliance to ISO/IEC 17025 – "General Requirements for the Competence of Calibration and Testing Laboratories". These accrediting bodies are signatories to the National Cooperation for Laboratory Accreditation (NACLA) Mutual Recognition Arrangement (MRA). AIHA is one of the five signatories to the MRA. NACLA, a non-profit corporation established in 1998, was founded by representatives of public and private sector organizations to provide coordination and focus for laboratory accreditation programs in the United States. NACLA evaluates U.S. accrediting bodies and grants recognition to those accrediting bodies found to be in compliance with NACLA procedures and the relevant international standards for competent accrediting bodies. Signatory accrediting bodies are considered to have demonstrated equivalent competence to the ISO/IEC Guide 58 – Calibration and Testing Laboratory Accreditation Systems – "General Requirements for Operation and Recognition" (soon to be ISO/IEC Standard 17011).

The AIHA laboratory accreditation programs began 30 years ago, and provide laboratory accreditation in four areas: Industrial Hygiene, Environmental Lead, Environmental Microbiology, and Food. All laboratories granted accreditation by AIHA are in compliance with the International Standard ISO/IEC 17025. The AIHA Food Laboratory Accreditation Program (FoodLAP) is a comprehensive food laboratory accreditation program for labs that perform tests on food products (including raw agricultural commodities), finished food products, and food ingredients.

Accreditation is offered in these three critical areas:

- Microbiology (bacteria, yeast, fungi, protozoa, and viruses such as Salmonella, Listeria, E. coli O157:H7, and Coliform, in various matrices such as meat or cereals)

- Chemistry (fat, moisture, protein, salt, sugars, dietary fiber, minerals, and vitamins, in matrices of meat, cereal, dairy, and feeds)

- Residue Chemistry (pesticides, sulfonamides, nitrosamines, and toxic elements [lead, arsenic, mercury]) in matrices of meat, poultry products, and fruits and vegetables

Laboratories are encouraged to seek accreditation in one, two, or all three-performance area offerings. Laboratories must be enrolled in proficiency testing in order to be eligible for accreditation.

With the laboratory's permission, the proficiency testing results are submitted to the AIHA from the proficiency testing providers used by the laboratories. Results are used to determine overall proficiency status to comply with the accreditation program requirements. Performance is monitored on a continuing basis.

The FDA also cites as a reason for not requiring laboratory accreditation the fact that "there are very few accrediting bodies qualified to accredit laboratories" and that only 10 to 15 percent of the more than 100 private laboratories are accredited.

AIHA responds to this concern with the view that the two U.S. accrediting authorities can handle the 100+ labs over the course of several years. In addition, an ISO/IEC Standard 17025 accreditation requirement would assure that additional non-U.S. laboratories could contribute capacity to the testing needs due to internationally recognized accreditation standards. In addition, the FDA in its proposal cited its "increased concern to protect our food supply and the potential for bioterrorism attacks". One of the most secure means of addressing this concern would be to limit the testing of imported food to U.S.-based accredited laboratories.

In conclusion, AIHA again strongly recommends that the proposed rule include a requirement that private laboratories be accredited. Review of analytical documentation by FDA staff is useful, but the optimum scenario would be laboratory accreditation plus oversight review by FDA staff.

Again, thank you for the opportunity to comment on this proposed rule. AIHA also offers to the FDA our expertise and worldwide recognition with laboratory accreditation in the hopes that this proposed rule successfully addresses the concerns with the validity of private labs used in connection with imported food.

Should you have any questions, please contact me.

Sincerely,

(signature)
Donna M. Doganiero, CIH

President

cc: AIHA Board of Directors